IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

MERCK & CIE, BAYER PHARMA AG and)
BAYER HEALTHCARE)
PHARMACEUTICALS INC.,)
) C.A. No. 13-1272-RGA
Plaintiffs,)
)
V.)
WATSON LABORATORIES, INC.,)
)
Defendant.)

ANSWER TO COMPLAINT, DEFENSES AND COUNTERCLAIMS BY DEFENDANT WATSON LABORATORIES, INC.

Defendant Watson Laboratories, Inc. ("Watson Labs"), hereby answers the Complaint of Plaintiffs Merck & Cie ("Merck"), Bayer Pharma AG and Bayer Healthcare Pharmaceuticals Inc. (collectively, "Bayer") (collectively, "Plaintiffs") as follows:

PARTIES

1. Plaintiff Merck & Cie ("Merck") is a Swiss corporation having a principal place of business at Weisshausmatte 6460 Altdorf, Switzerland.

ANSWER: Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations in paragraph 1 of the Complaint and therefore denies them.

2. Plaintiff Bayer Pharma AG ("Bayer Pharma"), formerly known as Schering AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

<u>ANSWER</u>: Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations in paragraph 2 of the Complaint and therefore denies them.

3. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare"), formerly known as Berlex, Inc., is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

ANSWER: Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations in paragraph 3 of the Complaint and therefore denies them.

4. On information and belief, Defendant Actavis, Inc. ("Actavis") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880. Defendant Actavis develops, manufactures and markets generic pharmaceutical products through its operating subsidiary Defendant Watson Laboratories, Inc.

<u>ANSWER:</u> The allegations in paragraph 4 of the Complaint are directed to a party that is no longer in this case, and therefore no response is required from Watson Labs. To the extent a response is required, Watson Labs denies all allegations in paragraph 4 of the Complaint.

5. On information and belief, Defendant Watson Laboratories, Inc. ("Watson Labs.") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

<u>ANSWER</u>: Watson Labs admits that it is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California 92880. Watson Labs denies all remaining allegations in paragraph 5 of the Complaint.

6. On information and belief, Defendant Watson Labs. is a wholly-owned subsidiary of Defendant Actavis, and the two have common officers and directors.

ANSWER: Watson Labs admits that it is a wholly-owned subsidiary of Actavis, Inc.

Watson Labs denies all remaining allegations in paragraph 6 of the Complaint.

7. On information and belief, Defendant Actavis directed, authorized, participated in, assisted and cooperated with Defendant Watson Labs. in all of the acts complained of herein. Hereinafter, Defendants Actavis and Watson Labs. are collectively referred to as "Watson."

ANSWER: Watson Labs admits that the Complaint purports to refer to Actavis and Watson Labs collectively as "Watson." The allegations in paragraph 7 of the Complaint are directed to a party that is no longer in this case, and therefore no response is required from Watson Labs. To the extent a response is required, Watson Labs denies all remaining allegations in paragraph 7 of the Complaint.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 8 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Watson Labs admits that the Complaint purports to state an action that arises under the patent laws of the United States of America, and that this Court has jurisdiction over the subject matter of this action with respect to Watson Labs. Watson Labs denies all remaining allegations in paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over Defendants Actavis and Watson Labs. by virtue of, *inter alia*, the fact that they regularly transact and solicit business in Delaware, have consented to jurisdiction in Delaware in cases arising out of the filing of their ANDAs, and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into Court here.

ANSWER: Paragraph 9 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, for the purpose of this case only, Watson Labs does not contest personal jurisdiction. With respect to the allegations in paragraph 9 of the Complaint that are asserted against a party that is no longer in this case, no response is required from Watson Labs. To the extent a response is required, Watson Labs denies all such allegations. Watson Labs denies all remaining allegations in paragraph 9 of the Complaint.

10. On information and belief, Actavis has consolidated its activities and financial results in its most recent SEC filings and Annual Report with, among other entities, Watson Labs.

ANSWER: The allegations in paragraph 10 of the Complaint are directed to a party that is no longer in this case, and therefore no response is required from Watson Labs. To the extent a response is required, Watson Labs denies all allegations in paragraph 10 of the Complaint.

11. On information and belief, Actavis and Watson Labs. earn revenue from the distribution in Delaware of generic pharmaceutical products that are manufactured by Watson Labs. On information and belief, various products for which Watson Labs. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware and elsewhere through a link provided on Actavis' website.

ANSWER: Watson Labs admits that it manufactures certain generic pharmaceutical products in the United States. Watson Labs admits that the website www.actavis.com lists products for which Watson Labs is the named abbreviated new drug application ("ANDA") applicant. With respect to the allegations in paragraph 11 of the Complaint that are asserted against a party that is no longer in this case, no response is required from Watson Labs. To the extent a response is required, Watson Labs denies all such allegations. Watson Labs denies all remaining allegations in paragraph 11 of the Complaint.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

ANSWER: Watson Labs will not contest venue for the purposes of this action. Paragraph 12 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Watson Labs denies all allegations contained in paragraph 12 of the Complaint.

BACKGROUND

13. Bayer HealthCare is the holder of approved New Drug Application ("NDA") No. 022532, for Beyaz®, which contains as active ingredients drospirenone, 17α -ethinyl estradiol, and levomefolate calcium. Beyaz® tablets have been approved by the United States Food and Drug Administration ("FDA") to prevent pregnancy in women who elect to use an oral contraceptive, and to provide a daily dose of folate supplementation. Beyaz® tablets are sold in the United States by Bayer HealthCare as a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of micronized drospirenone, 0.02 mg of micronized 17α -ethinylestradiol, and 0.451 mg levomefolate calcium plus 4 tablets comprising 0.451 mg levomefolate calcium.

ANSWER: Watson Labs admits that the FDA lists Bayer Healthcare as the holder of approved New Drug Application ("NDA") 022532 for Beyaz®. Watson Labs admits that the

Prescribing Information for Beyaz® states that Beyaz® contains drospirenone, ethinyl estradiol, and levomefolate calcium. Watson Labs admits that the Prescribing Information for Beyaz® states that Beyaz® is indicated for use by women to prevent pregnancy and raise folate levels in women who choose to use an oral contraceptive for contraception. Watson Labs admits that the Prescribing Information for Beyaz® states that the dosage form of Beyaz® "consists of 28 film-coated, biconvex tablets in the following order: 24 pink tablets, each containing 3 mg drospirenone (DRSP), 0.02 mg ethinyl estradiol (EE) as betadex clathrate and 0.451 mg levomefolate calcium, [and] 4 light orange tablets, each containing 0.451 mg levomefolate calcium." Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 13 of the Complaint and therefore denies them.

14. On information and belief, Watson submitted to the FDA Abbreviated New Drug Application ("ANDA") No. 203593 under the provisions of 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer HealthCare's Beyaz® tablets.

<u>ANSWER</u>: Watson Labs admits that pursuant to the applicable laws and regulations, it submitted ANDA No. 203593 to the FDA, seeking approval to engage in the commercial manufacture, use, or sale of the product described in ANDA No. 203593. Watson Labs denies all remaining allegations in paragraph 14 of the Complaint.

15. On information and belief, the composition of the product that is the subject of Watson's ANDA is for oral contraception in a human female and contains tablets comprising 3 mg of drospirenone, 0.02 mg of 17α -ethinylestradiol, and 0.451 mg levomefolate calcium, and tablets comprising 0.451 mg levomefolate calcium.

ANSWER: Watson Labs admits that ANDA No. 203593 seeks approval of a product for oral contraception in a human female. Watson Labs admits that ANDA No. 203593 describes a product containing tablets containing 3 mg of drospirenone, 0.02 mg of ethinyl estradiol, and

0.451 mg levomefolate calcium, and tablets containing 0.451 mg levomefolate calcium. Watson Labs denies all remaining allegations in paragraph 15 of the Complaint.

16. On information and belief, Watson's ANDA seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets comprising 3 mg of drospirenone, 0.02 mg of 17α -ethinylestradiol, and 0.451 mg levomefolate calcium, and 4 tablets comprising 0.451 mg levomefolate calcium (hereinafter "Watson's ANDA product").

ANSWER: Watson Labs admits that ANDA No. 203593 seeks approval of a 28-day oral contraceptive regimen that contains 24 tablets containing 3 mg of drospirenone, 0.02 mg of ethinyl estradiol, and 0.451 mg levomefolate calcium, and 4 tablets containing 0.451 mg levomefolate calcium. Watson Labs denies all remaining allegations in paragraph 16 of the Complaint.

17. On information and belief, on or about June 19, 2013, Watson sent a Notice Letter to Plaintiffs Merck, Bayer Pharma, and Bayer HealthCare, purporting to comply with the provisions of 21 U.S.C. $\S 355(j)(2)(B)$ and the FDA regulations relating thereto.

ANSWER: Watson Labs admits that it sent a Notice Letter on June 19, 2013 to Plaintiffs in compliance with applicable laws and regulations. Watson Labs denies all remaining allegations in paragraph 17 of the Complaint.

18. The patent-in-suit is U.S. Patent No. 6,441,168 (the "'168 Patent") (attached hereto as Exhibit 1). Inventors Rudolf Müller, Rudolf Moser, and Thomas Egger filed their application for this patent on April 17, 2000. The '168 Patent was issued August 27, 2002. Merck & Cie is the current owner of the '168 Patent.

ANSWER: Watson Labs admits that the Complaint alleges infringement of one patent, U.S. Patent No. 6,441,168 (the "'168 patent"). Watson Labs admits that Exhibit 1 to the Complaint purports to be a copy of the '168 patent. Watson Labs admits that the '168 patent on its face lists Rudolf Müller, Rudolf Moser, and Thomas Egger as the named inventors. Watson Labs admits that the '168 patent on its face states that Application No. 09/551,405 was filed on April 17, 2000, and that the '168 patent issued on August 27, 2002. Watson Labs lacks

knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 18 of the Complaint and therefore denies them.

19. Bayer Pharma is the exclusive licensee of the '168 Patent for the sectors of gynecology and andrology, for the indications fertility control, hormone therapy, and hormone replacement therapy (with the exception of oncological indications). Bayer Pharma is also the exclusive licensee of the '168 Patent for the indications listed above as a primary indication in combination with secondary indications within the same product.

<u>ANSWER</u>: Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations in paragraph 19 of the Complaint and therefore denies them.

20. Bayer HealthCare markets Beyaz® in the United States under Bayer Pharma's exclusive license.

<u>ANSWER</u>: Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the allegations in paragraph 20 of the Complaint and therefore denies them.

ALLEGED INFRINGEMENT OF UNITED STATES PATENT NO. 6,441,168

21. Plaintiffs incorporate all preceding paragraphs of this Complaint as if fully set forth herein.

<u>ANSWER</u>: Watson Labs incorporates by reference paragraphs 1-20 of this Answer to the Complaint as if fully set forth herein.

22. On information and belief, Watson's ANDA product infringes one or more claims of the '168 Patent.

ANSWER: Watson Labs denies all allegations in paragraph 22 of the Complaint.

23. The '168 Patent covers Bayer HealthCare's Beyaz® tablets and has been listed for the product in the FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book").

ANSWER: Watson Labs admits that the '168 patent is listed in the Orange Book for Beyaz®. Watson Labs lacks knowledge sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 23 of the Complaint and therefore denies them.

24. On information and belief, Watson submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '168 Patent.

ANSWER: Watson Labs admits that it submitted ANDA No. 203593 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of the tablets that are the subject of that ANDA before the expiration of the '168 patent. Watson Labs denies all remaining allegations in paragraph 24 of the Complaint.

25. On information and belief, Watson made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that, in its opinion, the '168 Patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product.

ANSWER: Watson Labs admits that its ANDA No. 203593 contains a certification pursuant to 21 U.S.C. § 355 (j)(2)(A)(vii)(IV) that in its opinion and to the best of its knowledge, the '168 patent is invalid, unenforceable, or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the tablets that are the subject of that ANDA. Watson Labs denies all remaining allegations in paragraph 25 of the Complaint.

26. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product before the expiration of the '168 Patent, Watson has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA product will also infringe one or more claims of the '168 Patent.

ANSWER: Watson Labs denies all allegations in paragraph 26 of the Complaint.

27. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Watson's ANDA shall be a date which is not earlier than April 17, 2020, the current expiration date of the '168 Patent, or any later date of exclusivity to which Plaintiffs become entitled.

ANSWER: Watson Labs denies all allegations in paragraph 27 of the Complaint.

28. On information and belief, when Watson filed its ANDA, it was aware of the '168 Patent and was aware that the filing of its ANDA with the request for its approval prior to the expiration of the '168 Patent constituted an act of infringement of the '168 Patent.

ANDA No. 203593. Watson Labs denies all remaining allegations in paragraph 28 of the Complaint.

29. This case is an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

ANSWER: Watson Labs denies all allegations in paragraph 29 of the Complaint.

PRAYER FOR RELIEF

Watson Labs denies that Plaintiffs are entitled to the relief requested in paragraphs A-E of the Complaint.

DEFENSES

Watson Labs sets forth the following affirmative and other defenses. Watson Labs reserves the right to allege additional defenses as they become known through the course of discovery. Watson Labs does not intend hereby to assume the burden of proof with respect to those matters on which, under law, Plaintiffs bear the burden of proof.

FIRST DEFENSE - NON-INFRINGEMENT OF U.S. PATENT NO. 6,441,168

Watson Labs does not infringe, induce infringement of, and/or contribute to the infringement of any valid, enforceable claim of the '168 patent.

SECOND DEFENSE – INVALIDITY OF U.S. PATENT NO. 6,441,168

One or more claims of the '168 patent are invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

COUNTERCLAIMS

Defendant/Counterclaimant Watson Laboratories, Inc. ("Watson Labs") hereby asserts Counterclaims against Plaintiffs/Counterdefendants Merck & Cie ("Merck"), Bayer Pharma AG and Bayer Healthcare Pharmaceuticals Inc. (collectively, "Bayer") (collectively, "Plaintiffs/Counterdefendants") as follows:

PARTIES

- 1. Watson Labs is a corporation organized and existing under the laws of the State of Nevada, having a place of business at 311 Bonnie Circle, Corona, California, 92880.
- 2. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Merck is a Swiss corporation having a principal place of business at Weisshausmatte 6460 Altdorf, Switzerland.
- 3. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.
- 4. On information and belief and based on Plaintiffs/Counterdefendants' allegations, Bayer Healthcare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 340 Changebridge Road, P.O. Box 1000, Montville, New Jersey 07045-1000.

JURISDICTION AND VENUE

- 5. These counterclaims seek a declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202.
- 6. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and 35 U.S.C. § 271(e)(2).
- 7. This Court has personal jurisdiction over Plaintiffs/Counterdefendants on the basis of, *inter alia*, their contacts with the District of Delaware relating to the subject matter of this action, including having filed this suit.

8. Venue is proper under 28 U.S.C. §§ 1391 and 1400(b), and by Plaintiffs/Counterdefendants' choice of venue.

BACKGROUND

- 9. This is an action based upon an actual controversy between the parties concerning the invalidity and noninfringement of U.S. Patent No. 6,441,168 ("the '168 patent") and Watson Labs' right to continue to seek approval of Abbreviated New Drug Application ("ANDA") No. 203593 for a drospirenone, ethinyl estradiol, levomefolate calcium product, and upon approval by the United States Food and Drug Administration ("FDA"), to manufacture, import, use, market, sell and/or offer to sell drospirenone, ethinyl estradiol, levomefolate calcium products in the United States.
- 10. Watson Labs submitted, and is continuing to seek FDA approval of, ANDA No. 203593. Watson Labs' ANDA No. 203593 seeks approval to engage in the commercial manufacture, use, and/or sale of products that Plaintiffs/Counterdefendants allege infringe the '168 patent.
- 11. The '168 patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for the drug Beyaz®.
- 12. On information and belief, and based on Plaintiffs/Counterdefendants' allegations, Bayer Healthcare Pharmaceuticals Inc. is the holder of New Drug Application No. 022532 for Beyaz® tablets containing the active ingredients drospirenone, ethinyl estradiol, and levomefolate calcium.
- 13. Plaintiffs/Counterdefendants caused the '168 patent to be listed in the Orange Book in association with Beyaz®.

- 14. As a consequence of listing the '168 patent in the Orange Book, Plaintiffs/Counterdefendants were and are representing to the world that the '168 patent claims Beyaz®, and that patent infringement actions relating to the '168 patent could reasonably be expected to be brought against unlicensed filers of ANDAs containing a certification pursuant to FDCA Section 505(j)(2)(A)(vii), Paragraph IV.
- 15. Watson Labs certified to the FDA in its ANDA No. 203593 that, in Watson Labs' opinion and to the best of its knowledge, its proposed drospirenone, ethinyl estradiol, levomefolate calcium products will not infringe any valid and/or enforceable claim of the '168 patent.
- 16. Watson Labs notified Plaintiffs/Counterdefendants of the factual and legal bases for Watson Labs' certification with respect to the '168 patent in a letter dated June 19, 2013 ("Notice Letter").
- 17. The Notice Letter included an offer of confidential access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).
- 18. Plaintiffs/Counterdefendants have filed in this Court an infringement action to enforce the '168 patent.
- 19. Watson Labs has denied that it has, continues to, or will infringe, induce infringement of, and/or contribute to the infringement of, any valid and enforceable claim of the '168 patent.
- 20. Watson Labs has further asserted that the '168 patent is invalid for failure to satisfy the provisions of one or more of Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

21. In view of the foregoing, a conflict of asserted rights has arisen between Watson Labs and Plaintiffs/Counterdefendants with respect to the noninfringement and invalidity of claims of the '168 patent, and as to Watson Labs' right to obtain FDA approval to engage in the commercial manufacture, importation, use, offer for sale, or sale of its drospirenone, ethinyl estradiol, levomefolate calcium products. An actual controversy therefore exists between Watson Labs and Plaintiffs/Counterdefendants.

FIRST COUNTERCLAIM – DECLARATION OF NON-INFRINGEMENT OF U.S. PATENT NO. 6,441,168

- 22. Watson Labs repeats and realleges paragraphs 1-21 of its Counterclaims as if set forth specifically herein.
- 23. Watson Labs does not infringe any valid, enforceable claim of the '168 patent, directly, indirectly, literally or under the doctrine of equivalents.
- 24. The sale, offer for sale, manufacture, importation, or use of Watson Labs' drospirenone, ethinyl estradiol, levomefolate calcium tablets will not constitute infringement of any valid, enforceable claim of the '168 patent, either directly, indirectly, literally or under the doctrine of equivalents.

SECOND COUNTERCLAIM – DECLARATION OF INVALIDITY OF U.S. PATENT NO. 6,441,168

- 25. Watson Labs repeats and realleges paragraphs 1-24 of its Counterclaims as if set forth specifically herein.
- 26. One or more claims of the '168 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112.

DEMAND FOR JUDGMENT

WHEREFORE, Watson Labs prays for the following relief:

- A. That all claims against Watson Labs be dismissed with prejudice, that all relief requested by Plaintiffs/Counterdefendants be denied, and that Plaintiffs/Counterdefendants take nothing by their Complaint;
- B. That a judgment be entered declaring that Watson Labs has not and does not infringe, directly, indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of United States Patent No. 6,441,168; that Watson Labs has a lawful right to obtain FDA approval of ANDA No. 203593; and further that Watson Labs has a lawful right to manufacture, import, use, sell and/or offer to sell its drospirenone, ethinyl estradiol, levomefolate calcium products in the United States once approved by the FDA;
- C. That a judgment be entered declaring that the claims of United States Patent No. 6,441,168 are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112;
- D. That Plaintiffs/Counterdefendants, their parents and/or subsidiaries, and their agents, representatives, attorneys and those persons in active concert or participation with them who receive actual notice thereof, be preliminarily and permanently enjoined from threatening or initiating infringement litigation against Watson Labs or any of its customers, dealers or suppliers, or any prospective or present sellers, dealers, distributors or customers of Watson Labs, or charging any of them either orally or in writing with infringement of United States Patent No. 6,441,168;

- E. That a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285, and that Watson Labs is entitled to recover its reasonable attorneys' fees upon prevailing in this action;
- F. That Watson Labs be awarded costs, attorneys' fees and other relief, both legal and equitable, to which they may be justly entitled; and
 - G. That Watson Labs be awarded such other and further relief as is just and proper.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

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Dated: August 19, 2013

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By: /s/ David E. Moore

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Attorneys for Defendant Watson Laboratories, Inc.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on August 19, 2013, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on August 19, 2013, the attached document was electronically mailed to the following person(s)

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